

AMENDED PAGE ONE OF THE SPECIFICATION
TRANSDERMAL PATCH FOR BOTULINUM TOXIN
ADMINISTRATION COMPOSITIONS

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by

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CROSS REFERENCE

This application is a divisional of pending application serial number 10/194,805, filed July 11, 2002.

15 The present invention relates to pharmaceutical compositions containing neurotoxins. In particular, the present invention relates to compositions containing clostridial neurotoxins, such as botulinum toxin, for transdermal topical administration to patients.

BACKGROUND

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Botulinum Toxin

25 The genus *Clostridium* has more than one hundred and twenty seven species, grouped according to their morphology and functions. The anaerobic, gram positive bacterium *Clostridium botulinum* produces a potent polypeptide neurotoxin, botulinum toxin, which causes a neuromuscular illness in humans and animals referred to as botulism. The spores of *Clostridium botulinum* are found in soil and can grow in improperly sterilized and sealed food containers of home based canneries, which are the cause of many of the cases of botulism. The effects of botulism typically appear 18 to 36 hours after eating the foodstuffs infected with a *Clostridium botulinum* culture or spores. The botulinum toxin can apparently pass unattenuated through the lining of the gut and attack peripheral motor neurons. Symptoms of botulinum toxin intoxication can progress from

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difficulty walking, swallowing, and speaking to paralysis of the respiratory muscles and death.

Botulinum toxin type A is the most lethal natural biological agent known
5 to man. About 50 picograms of a commercially available